UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

ERSTE-SPARINVEST KAPITALANLAGEGESELLSCHAFT m.b.H., Derivatively on Behalf of Cardinal Health, Inc., Plaintiff, v. DAVID J. ANDERSON, COLLEEN F. ARNOLD, GEORGE S. BARRETT, CARRIE S. COX, CALVIN DARDEN, BRUCE L. DOWNEY, PATRICIA A. HEMINGWAY HALL, CLAYTON M. JONES, GREGORY B. KENNY, DAVID P. KING, RICHARD C. NOTEBAERT, GLENN A. BRITT, JOHN F. FINN, DAVID W. RAISBECK, JEAN G. SPAULDING, DAVE BING, R. KERRY CLARK, GEORGE H. CONRADES, PHILIP L. FRANCIS, JOHN F. HAVENS, J. MICHAEL LOSH, JOHN B. MCCOY, MICHAEL O'HALLERAN, MATTHEW D. WALTER, AND ROBERT D. WALTER, Defendants, and CARDINAL HEALTH, INC., Nominal Defendant.	Case No. 2:15-cv-320 JURY TRIAL DEMANDED

VERIFIED SHARHOLDER DERIVATIVE COMPLAINT

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For Plaintiff Erste-Sparinvest Kapitalanlagegesellschaft m.b.H.'s ("Plaintiff") Verified Shareholder Derivative Complaint,[1] Plaintiff alleges the following upon personal knowledge as to itself, and upon information and belief as to all other allegations, based upon its attorneys' investigation of information pertinent to the claims herein alleged:

I. NATURE OF THE ACTION

1. This is a verified shareholder derivative action brought pursuant to Federal Rule of Civil Procedure 23.1 on behalf of nominal defendant Cardinal Health, Inc. ("Cardinal Health" or the "Company"), against the current members of the Company's Board of Directors (the "Board") and certain former directors and officers of the Company. Plaintiff seeks injunctive and other relief against Defendants on behalf of the Company for breaches of fiduciary duties owed to Cardinal Health arising out of the Company's repeated violations of federal and state law that required the Company to implement a system to detect and prevent the diversion of controlled substances into the illegal market. These breaches of fiduciary duties have substantially injured and will continue to substantially injure the Company.

2. Pursuant to *Rule* 23.1(b)(3)(A), Plaintiff made a demand on the Board by letter dated May 6, 2014, Exhibit 2, attached hereto (the "Demand Letter"), to conduct an investigation and commence legal action in good faith for remedial and other relief against current and former Cardinal Health directors and Defendants Colleen F. Arnold ("Arnold"), George S. Barrett ("Barrett"), Glenn A. Britt ("Britt"), Carrie S. Cox ("Cox"), Calvin Darden ("Darden"), Bruce L. Downey ("Downey"), John F. Finn ("Finn"), Gregory B. Kenny ("Kenny"), David P. King ("King"), Richard C. Notebaert ("Notebaert"), David W. Raisbeck ("Raisbeck"), Jean G. Spaulding ("Spaulding"), Dave Bing ("Bing"), R. Kerry Clark ("Clark"), George H. Conrades

[1] Plaintiff's Verification is provided in Exhibit 1, enclosed hereto.

("Conrades"), Philip L. Francis ("Francis"), John F. Havens ("Havens"), J. Michael Losh ("Losh"), John B. McCoy ("McCoy"), Michael O'Halleran ("O'Halleran"), Matthew D. Walter ("M. Walter"), and Robert D. Walter ("R. Walter") (collectively, the "Diversion Defendants") for the substantial unremediated injuries suffered by the Company as a result of their breaches of fiduciary duty. The Demand Letter also identified three specific issues requiring investigation.

3. Plaintiff's demand to commence legal action was wrongfully rejected by the Board by letter dated November 14, 2014.

4. The Board on May 6, 2014, November 14, 2014, and as of the date this complaint was filed, was comprised of Defendants David J. Anderson ("Anderson"), Arnold, Barrett, Cox, Darden, Downey, Patricia A. Hemingway Hall ("Hemingway Hall"), Clayton M. Jones ("Jones"), Kenny, King, and Notebaert (collectively, the "Demand Defendants").

5. There is no presumption in favor of the good faith of a special committee. The Demand Defendants' wrongful rejection of Plaintiff's demand constituted a breach of their fiduciary duties, and is not subject to judicial deference under the law of the Company's state of incorporation, Ohio.

6. Due to the Demand Defendants' wrongful refusal to act, Plaintiff now brings this action to correct the harm the Diversion Defendants have caused the Company.

7. As current or past directors and officers of Cardinal Health, each of the Defendants owes and owed Cardinal Health the fiduciary duties of loyalty and due care in the management and administration of the Company's affairs. As more fully described herein, the Diversion Defendants caused and/or allowed Cardinal Health to engage in repeated and persistent violations of federal and state law regarding the distribution and sale of controlled

substances. As a result of these actions, Cardinal Health has been materially and substantially damaged.

8. As detailed herein, the Diversion Defendants caused and/or allowed Cardinal Health to disregard its obligations regarding the distribution and sale of controlled substances under federal and state law for a substantial period of time, despite knowing that Cardinal Health was violating the law and faced substantial monetary fines and other damage in connection with its misconduct. The wrongdoing detailed herein was not misconduct perpetrated at the bottom levels of the Company hidden from the view of senior managers and directors. The Diversion Defendants' actions (and inaction) were serious and substantial violations of their fiduciary duties to the Company.

II. JURISDICTION AND VENUE

9. This Court has jurisdiction over the subject matter of this action under and pursuant to 28 U.S.C. §§ 1332(a) and 1401 because this is an action for, *inter alia*, damages in excess of $75,000, exclusive of interest and costs, there is complete diversity of citizenship, and Cardinal Health is incorporated in Ohio and maintains its principal place of business therein.

10. This action is not a collusive one to confer jurisdiction on a Court of the United States that it would not otherwise have.

11. Venue is proper in this District because Cardinal Health is incorporated in Ohio and maintains its principal place of business in this District.

III. THE PARTIES

A. *Plaintiff*

12. Plaintiff is an owner of Cardinal Health stock and was an owner of Cardinal Health stock at all times relevant to the Defendants' wrongful conduct alleged herein. Plaintiff is a citizen of the Republic of Austria.

B. *Nominal Defendant*

13. Nominal Defendant Cardinal Health is an Ohio corporation and maintains its principal executive offices at 7000 Cardinal Place, Dublin, Ohio 43017. The Company was founded in 1971 and has been distributing pharmaceuticals since 1979. Cardinal Health is a $103 billion health care services company that provides pharmaceuticals and medical products to more than 60,000 locations each day. Cardinal Health is one of the largest wholesale pharmaceutical drug distributors in the United States. Through its distribution facilities, the Company distributes, among other things, controlled substances to its customers throughout the country. Cardinal Health also is a leading manufacturer of medical and surgical products, including gloves, surgical apparel and fluid management products. Additionally, the Company supports the growing diagnostic industry by supplying medical products to clinical laboratories and operating the nation's largest network of radiopharmacies that dispense products to aid in the early diagnosis and treatment of disease. Cardinal Health is ranked number twenty-one on the Fortune 500, and employs more than 30,000 people worldwide. Cardinal Health's common stock is traded on the NYSE under the ticker symbol "CAH."

C. *The Defendants*

1. <u>Current Directors</u>

14. Defendant Anderson has served as a Cardinal Health director since April 2014. Anderson is a member of the Company's Audit Committee. Anderson has served on the Audit

Committee since April 25, 2014. Upon information and belief, Anderson is a citizen of Connecticut.

15. Defendant Arnold has served as a Cardinal Health director since August 2007. Arnold has been a member of the Company's Nominating and Governance Committee since May 4, 2010 (the "Governance Committee"). Arnold served on the Compensation Committee from at least 2007 until February 2009 and on the Audit Committee from February 2009 until February 2010. Upon information and belief, Arnold is a citizen of Connecticut.

16. Defendant Barrett has served as a Cardinal Health director and as Chairman of the Board and Chief Executive Officer ("CEO") since August 2009. Barrett has been Chair of the Company's Executive Committee since August 2009. Upon information and belief, Barrett is a citizen of Ohio.

17. Defendant Cox has served as a Cardinal Health director since December 2009. Cox is a member of the Company's Human Resources and Compensation Committee (the "Compensation Committee"). Cox has served on the Compensation Committee since February 5, 2014 and served as a member of the Company's Audit Committee from 2010 until at least 2013. Upon information and belief, Cox is a citizen of Florida.

18. Defendant Darden has served as a Cardinal Health director since 2005. Darden has been a member of the Company's Compensation Committee since 2005. Upon information and belief, Darden is a citizen of Georgia.

19. Defendant Downey has served as a Cardinal Health director since August 2009. Downey has been a member of the Company's Audit Committee since August 2009. Upon information and belief, Downey is a citizen of Virginia.

20. Defendant Hemingway Hall has served as a Cardinal Health director since 2013. Hemingway Hall has served on the Audit Committee since November 6, 2013. Upon information and belief, Hemingway Hall is a citizen of Florida.

21. Defendant Jones has served as a Cardinal Health director since 2012. Jones is Chair of the Audit Committee. Jones has served as a member of the Audit Committee since February 5, 2014 and as Chair of the Audit Committee since June 27, 2014. Upon information and belief, Jones is a citizen of Iowa.

22. Defendant Kenny has served as a Cardinal Health director since August 2007. Kenny served as Chair of the Company's Compensation Committee until November 1, 2014, and has served on the Compensation Committee since at least 2008. Kenny has also been a member of the Governance Committee since February 2009, the Executive Committee since at least 2008, and the Audit Committee since at least 2007. Kenny has served as Lead Director and Chair of the Governance Committee since November 1, 2014. Upon information and belief, Kenny is a citizen of Ohio.

23. Defendant King has served as a Cardinal Health director since September 2011. King has served as a member of the Company's Audit Committee since at least 2012. King has served as a member of the Compensation Committee since November 6, 2013 and has served as Chair of the Compensation Committee since November 1, 2014. Upon information and belief, King is a citizen of North Carolina.

24. Defendant Notebaert has served as a Cardinal Health director since 1999. Notebaert is a member of the Company's Compensation Committee and also is a member of the Governance Committee. Notebeart has served as a member of the Executive Committee since at least 2007. Upon information and belief, Notebaert is a citizen of Illinois.

2. Former Directors

25. Defendant Britt served as a Cardinal Health director from October 2009 until June 2014. Britt was a member of the Company's Audit Committee since October 2009 and was appointed Chair since at least 2012. Britt also was a member of the Executive Committee. Upon information and belief, Britt is a citizen of New York.

26. Defendant Finn served as a Cardinal Health director from 1994 until November 1, 2014. Finn was a member of the Company's Audit Committee since at least 2004 and served as Chair from at least 2005 until 2008 and then again in 2009. Finn also was a member of the Governance Committee since at least 2004 and Chair of the Governance Committee since November 2012. Finn was a member of the Executive Committee from at least 2004 until November 2007 and then again from August 2009 until at least 2014. Upon information and belief, Finn is a citizen of Ohio.

27. Defendant Raisbeck served as a Cardinal Health director from 2002 until 2012. Raisbeck was Chair of the Company's Governance Committee beginning July 2009 and was a member of the Compensation Committee since August 2009, the Audit Committee from at least 2004 until 2010, and the Executive Committee since July 2009. Upon information and belief, Raisbeck is a citizen of Florida.

28. Defendant Spaulding served as a Cardinal Health director from 2002 until at least 2013. Spaulding was a member of the Company's Compensation Committee since at least 2004. Upon information and belief, Spaulding is a citizen of North Carolina.

29. Defendant Bing served as a Cardinal Health director from 2000 until his retirement in 2005. Bing was a member of the Company's Audit Committee at the time of his retirement. Upon information and belief, Bing is a citizen of Michigan.

30. Defendant Clark served as a Cardinal Health director from April 2006 until he retired in August 2009. Clark was the Company's President and CEO beginning April 2006. During his time at the Company, Clark served on the Executive Committee and was Chair from 2006 until August 2009. Upon information and belief, Clark is a citizen of Ohio.

31. Defendant Conrades served as a Cardinal Health director from April 1999 until his term as a director expired in November 2008. During his time at the Company, Conrades served on the Audit Committee since at least 2004, the Executive Committee since at least 2004, and the Governance Committee since at least 2004 and was Chair from at least 2004. Upon information and belief, Conrades is a citizen of Florida.

32. Defendant Francis served as a Cardinal Health director from 2006 until he resigned from the Board in August 2009. During his time at the Company, Francis was a member of the Audit Committee since 2006. Upon information and belief, Francis is a citizen of Arizona.

33. Defendant Havens served as a Cardinal Health director from 1979 until November 2006. Havens was a member of the Company's Governance Committee and the Compensation Committee since at least 2004. Upon information and belief, Havens is a citizen of Ohio.

34. Defendant Losh served as a Cardinal Health director from 1996 until he resigned from the Board in August 2009. Losh was the Company's Chief Financial Officer ("CFO"), on an interim basis, from July 2004 to May 2005. While at the Company, Losh was a member of the Audit Committee from at least 2007 until 2009 and served as Chair since at least 2008, and also served on the Governance Committee and the Executive Committee since 2008. Upon information and belief, Losh is a citizen of Michigan.

35. Defendant McCoy served as a Cardinal Health director from 1987 until his retirement in July 2009. During his time at the Company, McCoy served on the Executive Committee since at least 2004 until 2009, the Compensation Committee since at least 2004 and was Chair since at least 2004, and the Governance Committee since at least 2004 and served as Chair from at least 2004 until 2009. Upon information and belief, McCoy is a citizen of Michigan.

36. Defendant O'Halleran served as a Cardinal Health director from 1999 until he resigned from the Board in August 2009. While at the Company, O'Halleran was a member of the Audit Committee since at least 2004. Upon information and belief, O'Halleran is a citizen of Wisconsin.

37. Defendant M. Walter served as a Cardinal Health director from 2002 until January 2008. Upon information and belief, M. Walter is a citizen of Florida.

38. Defendant R. Walter served as a Cardinal Health director from when he founded the Company in 1971, as Cardinal Foods, until his term as a director expired in November 2008. R. Walter served as the Company's Executive Chairman of the Board from April 2006 until November 8, 2007 and as Chairman and CEO from 1971 to April 2006. From November 2007 until June 2008, R. Walter served as Executive Director. While at the Company, R. Walter was a member of the Company's Executive Committee since at least 2004 and served as Chair in 2006. Upon information and belief, R. Walter is a citizen of Ohio.

39. The defendants referred to in paragraphs 14 to 24 are collectively referred to herein as the "Demand Defendants."

40. The defendants referred to in paragraphs 15-19, 22-38 are collectively referred to herein as the "Diversion Defendants."

41. The defendants referred to in paragraphs 15 to 38 are collectively referred to herein as the "Defendants."

IV. FACTUAL ALLEGATIONS

A. *Background*

42. The Controlled Substances Act ("CSA") creates restrictions on the manufacture, distribution, and dispensing of legally produced controlled substances. The U.S. Drug Enforcement Agency ("DEA") enforces the provisions of the CSA. Federal regulations require distributors of controlled substances to register with the DEA and maintain effective controls against the diversion of controlled substances into other than legitimate medical, scientific, and industrial channels. Moreover, such distributors must design and operate systems to disclose suspicious orders of controlled substances and notify the DEA of such orders.[2]

43. Under the CSA, the DEA may revoke or suspend an entity's registration for, *inter alia*, committing "such acts as would render his registration . . . inconsistent with the public interest." Typically, before suspending or revoking a registration, the DEA must issue an order to show cause, outlining its basis for the proceedings. However, in instances where the DEA has reason to believe that a registrant's continued operation would pose "an imminent danger to the public health or safety," the DEA may suspend the entity's registration immediately by issuing an Immediate Suspension Order ("ISO") pursuant to Section 824(d) of the CSA. An ISO will remain in effect "until the conclusion of such proceedings, including judicial review thereof, unless sooner withdrawn by the Attorney General or dissolved by a court of competent jurisdiction."

[2] Pursuant to 21 C.F.R. § 1301.74, "[s]uspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."

44. In late 2007, the DEA issued ISOs to three of Cardinal Health's drug distribution facilities, including its drug distribution facility located in Lakeland, Florida (the "Lakeland Facility"). The DEA issued the ISOs based on investigations that disclosed, among other things, that the Lakeland Facility failed to maintain effective controls against the diversion of controlled substances into the illicit market. Not long after the issuance of the three ISOs, in January 2008, the DEA issued an order instructing Cardinal Health to show cause as to why the DEA should not revoke one of its facilities' certificates of registration, based on the facility's failure to maintain effective controls against diversion.

45. As a result of the conduct that was the subject of the ISOs and the order to show cause, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA on September 30, 2008 (the "MOA"), in which Cardinal Health explicitly agreed, among other things, to maintain a compliance program designed to detect and prevent the diversion of controlled substances, as required under federal law and DEA regulations. The MOA was signed by Diversion Defendant Clark, Cardinal Health's former Chairman and CEO, on behalf of the Company. Additionally, Cardinal Health agreed to pay a civil fine of $34 million which, at the time, was the largest fine in United States history associated with a DEA registration suspension.

46. Despite Cardinal Health's previous and repeated violations of federal regulations and the Company's entry into the MOA, the Company did not implement an adequate system to detect and prevent diversion. Rather, not long after entering into the MOA, and after the DEA repeatedly notified Cardinal Health of its need to exercise greater diligence at its Lakeland Facility to detect suspicious activity by its customers, the DEA issued an ISO regarding the Lakeland Facility on February 2, 2012 (the "2012 ISO"). Once again, the DEA concluded that

the Lakeland Facility's continued registration posed an imminent danger to public health and safety.

47. As a result of the Company's continuous failure to comply with federal regulations – and violation of the terms of the MOA – Cardinal Health again faced substantial fines, as well as loss of business, damage to the Company's reputation, and significant attorneys' fees. Litigation concerning the 2012 ISO resulted in a May 15, 2012, settlement with the DEA pursuant to which Cardinal Health agreed to a two-year suspension of the Lakeland Facility's DEA registration to ship controlled medicines from the facility. Cardinal Health also agreed, as it did in 2008, to improve its anti-diversion procedures.

48. Jon Giacomin ("Giacomin"), CEO of Cardinal Health's Pharmaceutical Segment and President of U.S. Pharmaceutical Distribution, stated that as a result of the 2012 Lakeland Facility ISO, Cardinal Health's business reputation would be significantly tarnished, and customers would take their entire pharmaceutical business away from Cardinal Health. He anticipated that the delays would cause some of Cardinal Health's customers to leave Cardinal Health permanently for other distributors, as occurred following the 2007 Lakeland Facility ISO, and that the 2012 ISO will likely would have an even greater impact than did the 2007 ISO. Exhibit 3, ¶ 20, attached hereto.

49. The Company acknowledged in its U.S. Securities and Exchange Commission ("SEC") filings, most recently in its Form 10-Q for the period ended September 30, 2014, filed with the SEC on November 5, 2014, that "[t]he [May 15, 2012] settlement agreement did not foreclose the possibility of the U.S. Department of Justice (the 'DOJ') seeking civil fines in Florida or elsewhere for the conduct covered by the settlement agreement. In that regard, we are continuing to provide information to and engage in discussions with several offices of the DOJ,

including preliminary discussions regarding the feasibility of a settlement, and have accrued $27 million for this matter." Thus, the Company may be further damaged by its failure to comply with applicable federal law.

50. A verified shareholder derivative complaint was filed with this Court following the Company's May 15, 2012, settlement with the DEA alleging breaches of fiduciary duties by the Diversion Directors owed to Cardinal Health arising out of the Company's repeated violations of federal regulations that required the Company to implement a system to detect and prevent the diversion of controlled substances into the illegal market. *Stanley v. Arnold et al*., 12-cv-482-SSB-KLL (S.D. Ohio June 22, 2012) (Exhibit 4, attached hereto).

51. The complaint in *Stanley* was dismissed upon the motions of nominal defendant Cardinal Health and the Diversion Defendants for lack of standing because the plaintiff failed to allege with particularity that demand on the Board would be futile. *Stanley v. Arnold*, 2012 U.S. Dist. LEXIS 152096 (S.D. Ohio Oct. 23, 2012). The decision was affirmed in an unpublished opinion. *Stanley v. Arnold*, 531 Fed. Appx. 695 (6th Cir. 2013) (*per curiam*).[3]

52. By letter dated May 6, 2014, Plaintiff Erste formally demanded that the Board "investigate and commence legal action for remedial and other relief" against the Diversion Directors "for violating their fiduciary duties in connection with the allegations contained in the Verified Complaint in the case captioned *Stanley* v. *Arnold*" and for certain other allegations specified in the letter. Exhibit 2.

[3] A similar derivative complaint was filed in 2012 in the Court of Common Pleas, Delaware County, Ohio. It also was dismissed on demand futility grounds. *Himmel v. Barrett*, Case No. 12-CV-A-060663 (Ohio Ct. Comm. Pleas July 9, 2013).

53. By letter dated November 14, 2014, Plaintiff Erste was advised by Stephen T. Falk ("Falk"), the Company's Executive Vice President, General Counsel & Secretary that its demand was rejected by the Board. Exhibit 5, attached hereto.

54. The November 14, 2014, letter was completely devoid of details regarding the special committee and its work.

55. The only information Erste has been able to obtain about the special committee is from the Company's annual shareholder proxies, Schedule 14A, filed with the SEC on September 17, 2013 and September 16, 2014, which disclosed that Demand Defendant Jones and Demand and Diversion Defendant King received a total of $20,000 each for their service on the special committee.

B. *The Lakeland Facility*

56. Cardinal Health's Pharmaceutical segment currently operates twenty-one primary pharmaceutical distribution facilities, three specialty distribution facilities, and one national logistics center, all of which are registered with the DEA. The Lakeland Facility, located at 2045 Interstate Drive, Lakeland, Florida 33805, distributes Schedule II, III, IV, and V controlled substances. According to Giacomin, the Lakeland Facility "distributes a very large volume of prescription drugs and controlled substances in Florida. . . . The Lakeland facility is thus one of the largest wholesale prescription drug distributors in Florida." Exhibit 3, ¶ 5.

C. *The 2007-08 ISOs and Order to Show Cause Directed to Cardinal Health*

57. Based on findings from DEA investigations, between November 28, 2007, and December 7, 2007, the DEA issued three ISOs to Cardinal Health in connection with three distribution facilities whose continued registration with the DEA constituted an imminent danger to public health and safety.

58. On November 28, 2007, the DEA issued an ISO to Cardinal Health in connection with its distribution center in Auburn, Washington (the "Auburn Facility"), immediately suspending the facility's Certificate of Registration because its continued registration constituted "an imminent danger to public health and safety." According to the ISO, the Auburn Facility repeatedly "distributed unusually large amounts of hydrocodone" to Horen's Drugstore, Inc. ("Horen's Drugstore")—distributing 600,000 dosage units of hydrocodone to Horen's Drugstore from March 2007 through September 2007—and "*disregard[ed] the clear indications that Horen's Drugstore was engaged in the diversion of controlled substances*[.]" (Emphasis added).

59. Horen's Drugstore was Cardinal Health's largest purchaser of combination hydrocodone products in 2007, and according to the ISO, it was "a pharmacy engaged in a scheme to dispense controlled substances based on prescriptions that are issued for other than a legitimate medical purpose and by physicians acting outside the usual course of professional practice. This pharmacy dispensed excessive amounts of hydrocodone based on illegitimate prescriptions originating from rogue Internet pharmacy websites, in violation of applicable Federal and State law." The DEA found that Cardinal Health "failed to maintain effective controls against diversion of a particular controlled substance into other than legitimate medical, scientific and industrial channels," and concluded that its continued registration with the DEA constituted "an imminent danger to the public health and safety."

60. On December 5, 2007, the DEA issued an ISO to Cardinal Health regarding the Lakeland Facility (the "Lakeland ISO"). Pursuant to the Lakeland ISO, Cardinal Health was notified of the immediate suspension of the Lakeland Facility's Certificate of Registration because its "continued registration constitute[d] an imminent danger to public health and safety."

61. The Lakeland ISO detailed how, from August 2005 through October 2007, Cardinal Health failed to maintain effective controls against the diversion of hydrocodone into other than legitimate medical, scientific and industrial channels, in violation of the CSA:

> From August 2005 through October 2007, *Respondent distributed over 8,000,000 dosage units of combination hydrocodone products to customers that it knew or should have known were diverting hydrocodone into other than legitimate medical, scientific and industrial channels*. Hydrocodone, in the formulation that Respondent distributed to these customers, is a Schedule III narcotic controlled substance that is addictive and widely abused.
>
> Many of Respondent's largest purchasers of combination hydrocodone products were pharmacies engaged in a scheme to distribute controlled substances based on purported prescriptions that are issued for other than a legitimate medical purpose and by physicians acting outside the usual course of professional practice. These pharmacies distributed millions of dosage units of hydrocodone based on illegitimate prescriptions originating from rogue Internet pharmacy websites, in violation of applicable Federal and State law. . . .

(Emphasis added).

62. According to the Lakeland ISO, Cardinal Health distributed hydrocodone to various pharmacies even though it knew that many of the orders were of an unusual size and were "suspicious" as defined in 21 C.F.R. § 1301.74(b). The ISO explained that Cardinal Health repeatedly supplied the pharmacies "*with excessive amounts of hydrocodone* despite the substantial guidance provided to Respondent by DEA regarding identifying rogue pharmacies engaged in Internet diversion schemes, and despite the public information readily available to Respondent regarding many of its pharmacy customers' association with rogue Internet pharmacy websites, and despite the suspicious nature of the orders placed by these pharmacies." (Emphasis added).

63. For example, Cardinal Health distributed 1,213,200 dosage units to Q-R-G, Inc. from February to June 2006. Moreover, the Company distributed 1,148,100 dosage units to United Prescription Services, Inc. from July to October 2006.

64. The Lakeland ISO further detailed that on September 1, 2006, Eric Brantley, Manager of Quality and Regulatory Affairs for Cardinal Health, sent an email to the DEA's E-Commerce Section, stating that Cardinal Health discontinued its sales of controlled substances to thirteen Internet pharmacies, including RKR Holdings, Inc. ("RKR Holdings"). Nevertheless, from September 1, 2006, to January 31, 2007, Cardinal Health distributed 393,600 dosage units of combination hydrocodone products to RKR Holdings.

65. The DEA concluded in the Lakeland ISO that Cardinal Health "failed to maintain effective controls against diversion and that the continued registration of Respondent would be otherwise inconsistent with the public health and safety[,]" and "Respondent's continued registration while these proceedings are pending would constitute an imminent danger to the public health and safety *because of the substantial likelihood that Respondent will continue to divert large quantities of controlled substances*." (Emphasis added).

66. Two days after the Lakeland ISO was issued, on December 7, 2007, the DEA issued an ISO to Cardinal Health because, from January 2005 to August 2007, its distribution center in Swedesboro, New Jersey (the "Swedesboro Facility") "distributed over 4.5 million dosage units of combination hydrocodone products to customers that it knew or should have known were diverting hydrocodone into other than legitimate medical, scientific and industrial channels." The ISO stated that "[s]ome of Respondent's largest purchasers of combination hydrocodone products were pharmacies engaged in a scheme to distribute controlled substances based on purported prescriptions that were issued for other than a legitimate medical purpose and by physicians acting outside the usual course of professional practice."

67. As described in the Swedesboro Facility ISO, "Respondent repeatedly distributed hydrocodone combination products to pharmacies engaged in the diversion of controlled

substances. . . . Respondent continually supplied these pharmacies with excessive amounts of hydrocodone under circumstances in which Respondent knew or should have known that these pharmacies were diverting hydrocodone into other than legitimate medical, scientific, and industrial channels." The DEA ordered the immediate suspension of the Swedesboro Facility's Certificate of Registration because its continued registration constituted "an imminent danger to the public health and safety."

68. Following the issuance of the three ISOs to Cardinal Health, on January 30, 2008, the DEA issued an Order to Show Cause that provided Cardinal Health an opportunity to show cause as to why the DEA should not revoke the Certificate of Registration assigned to the Company's Stafford, Texas distribution center (the "Stafford Facility"). According to the Order to Show Cause, the Company distributed approximately 1,381,500 dosage units of hydrocodone to Richmond Pharmacy from January 2, 2007 to September 11, 2007, which significantly exceeded, on a daily basis, the daily limit set by Cardinal Health for its retail pharmacy customers. Moreover, the Company shipped 12,000 dosage units of hydrocodone to Richmond Pharmacy three days after being notified that Richmond Pharmacy surrendered its DEA registration and was no longer authorized to order or dispense controlled substances.

69. Cardinal Health's policy was to limit a retail pharmacy customer's purchases of hydrocodone products to 800 dosage units per day. Nevertheless, Cardinal Health frequently distributed hydrocodone in quantities that greatly exceeded that limit. For example, the Company distributed 66,000 dosage units of hydrocodone to Richmond Pharmacy on September 4, 2007; 48,000 dosage units on September 10, 2007; and 24,000 dosage units on September 11, 2007.

70. The Order to Show Cause stated:

> Registrant [Cardinal Health] distributed massive amounts of particular controlled substances to retail pharmacy customers without maintaining adequate controls to detect and prevent the diversion of controlled substances. For example, from January 2007 through September 2007, Registrant distributed nearly 21 million dosage units of hydrocodone to its retail pharmacy customers. Despite distributing such a large quantity of hydrocodone – a highly addictive and widely abused schedule III controlled substances – Registrant did not have sufficient policies and procedures that were in effect; and failed to provide its employees with the necessary training and resources to detect and prevent diversion.
>
> *Registrant's distributions of controlled substances to Richmond Pharmacy, AK Pharmacy, and others, were under circumstances that clearly indicated that the pharmacies were engaged in the widespread diversion of controlled substances*.

(Emphasis added).

71. Moreover, the Order to Show Cause set forth that:

> Notwithstanding the large quantities of controlled substances ordered by these pharmacies, Registrant failed to conduct meaningful due diligence to ensure that the controlled substances were not diverted into other than legitimate channels. Moreover, Registrant continued to supply the pharmacies with controlled substances without conducting due diligence, notwithstanding that the pharmacies were ordering controlled substances in quantities that far exceeded what traditional retail pharmacies order; that the pharmacies were ordering controlled substances on a more frequent basis than Registrant's traditional retail pharmacy customers; and that Registrant was supplying an inordinate amount of controlled substances versus non-controlled substances to these pharmacies.
>
> The direct and foreseeable consequence of Registrant's failure to conduct appropriate due diligence was the likely diversion of millions of dosage units of particular controlled substances.

72. Following the three ISOs and the Order to Show Cause, the DEA and Cardinal Health entered into the MOA on September 30, 2008. The MOA discussed the three ISOs and the Order to Show Cause, as well as the DEA's allegations that "Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities" located in McDonough, Georgia (the "McDonough Facility"), Valencia, California (the "Valencia Facility"), and Denver, Colorado (the "Denver Facility").

73. Pursuant to the MOA, Cardinal Health agreed to "maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations." Specifically:

> This program shall include procedures to review orders for controlled substances. Orders that exceed established thresholds and criteria will be reviewed by a Cardinal employee trained to detect suspicious orders for the purposes of determining whether (i) such orders should not be filled and reported to the DEA or (ii) based on a detailed review, the order is for a legitimate purpose and the controlled substances are not likely to be diverted into other than legitimate medical, scientific, or industrial channels. Orders identified as suspicious will be reported to the DEA as discussed in subsection II(1)(c). This compliance program shall apply to all current and future Cardinal distribution centers registered with the DEA in the United States and its territories and possessions. Cardinal acknowledges and agrees that the obligations undertaken in this subparagraph do not fulfill the totality of its obligations to maintain effective controls against the diversion of controlled substances or to detect and report to DEA suspicious orders for controlled substances.

74. The MOA detailed additional obligations for Cardinal Health, including, *inter alia*, that:

(a) "On a monthly basis, Cardinal shall provide DEA Headquarters with a report of all sales transactions of controlled substances, carisoprodol, and tramadol";

(b) "Cardinal shall inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b)";

(c) "Cardinal agrees to the continued suspension of its authority to handle controlled substances at its Lakeland, Auburn, and Swedesboro facilities until October 1, 2008, or until such time that the parties execute this Agreement";

(d) "Cardinal agrees that any express or implied approval by DEA of any previously implemented system to detect and report suspicious orders, is hereby rescinded and is of no legal effect with respect to Cardinal's obligations to detect and report suspicious orders in accordance with 21 C.F.R. § 1301.74(b)[]"; and

(e) "Cardinal's policy and procedure is to cooperate with the government in any investigation. Cardinal agrees to reasonably cooperate with DEA, the United States Attorneys' Offices, and any other Federal, state, or local law

> enforcement agency investigating or prosecuting Cardinal's customers for alleged violations or activities related to the Covered Conduct[.]"

75. Additionally, Cardinal Health agreed that:

> [W]ithin 180 days of the Effective Date of this Agreement it will review distributions of oxycodone, hydrocodone, alprazolam, and phentermine to retail pharmacy customers and physicians for the 18-month period immediately preceding the execution of this Agreement and identify any current customer whose purchases of oxycodone, hydrocodone, alprazolam, and phentermine exceeded the thresholds established in its compliance program on the date of such review. To the extent it has not otherwise done so, Cardinal shall conduct an investigation for each customer where such review reveals purchasing patterns substantially deviating from the normal purchasing patterns, and take appropriate action as required by this Agreement, DEA regulations and other procedures established under Cardinal's compliance program.

76. Moreover, Cardinal Health agreed to pay, pursuant to 21 U.S.C. § 842(c), a civil fine of $34 million for violations of 21 U.S.C. § 842(a)(5), to settle claims for failing to report suspicious orders of controlled substances.

77. The MOA was signed by, among others, Diversion Defendant Clark, on behalf of Cardinal Health.

78. DOJ and Cardinal Health also entered into a settlement agreement which, among other things, specifically set out what portions of the $34 million civil penalty were allocated to which Cardinal Health distribution facilities.

79. Specifically, the $34 million was allocable as follows: (i) $3 million for conduct alleged to have taken place within the District of New Jersey (the Swedesboro Facility); (ii) $16 million for conduct alleged to have taken place within the Middle District of Florida (the Lakeland Facility); (iii) $8 million for conduct alleged to have taken place within the Southern District of Texas (the Stafford Facility); (iv) $3.5 million for conduct alleged to have taken place within the Western District of Washington (the Auburn Facility); (v) $1 million for conduct alleged to have taken place within the District of Colorado (the Denver Facility); (vi) $1.5

million for conduct alleged to have taken place within the Northern District of Georgia (the McDonough Facility); and (vii) $1 million for conduct alleged to have taken place within the Central District of California (the Valencia Facility).

80. The largest portion of the fine by far was attributable to the Lakeland Facility.

81. This agreement also was signed by, among others, Diversion Defendant Clark on behalf of Cardinal Health.

82. In total, the DEA had reason to believe that seven of Cardinal Health's twenty-seven then-registered distribution centers were not adhering to their obligations as registrants. This was nearly *twenty-five percent* of Cardinal Health's registered distribution centers.

83. The Lakeland ISO was lifted on October 2, 2008, which was nearly ten months after the issuance of the ISO on December 5, 2007.

D. *Cardinal Health's Subsequent Violations of the CSA*

84. Between October 2008 and December 2011, the DEA investigated the Lakeland Facility's distribution of oxycodone to its top four Florida retail customers: (i) Holiday CVS, L.L.C., CVS #00219 in Sanford ("CVS 219"); (ii) Holiday CVS, L.L.C., CVS # 05195 in Sanford ("CVS 5195"); (iii) Caremed Health Corporation, Brooks Pharmacy in Bonita Springs ("Caremed"); and (iv) Gulf Coast Pharmacy in Fort Myers ("Gulf Coast").

85. According to a declaration of Joseph Rannazzisi, a Deputy Assistant Administrator for the DEA's Office of Diversion Control (the "Rannazzisi Declaration," attached hereto as Exhibit 6),[4] submitted in connection with Defendants' Opposition to Plaintiff's Motion for Preliminary Injunction (the "Opposition Brief") filed in *Cardinal Health, Inc. v. Holder*, Case No. 1:12-cv-00185 (D.D.C.), between October 2008 and December 2011, among other things,

[4] The facts set forth in the Rannazzisi Declaration are incorporated herein by reference.

the DEA: conducted compliance reviews at Cardinal Health's distribution centers; interviewed Cardinal Health employees; met with representatives of Cardinal Health; issued administrative inspection warrants ("AIW") to CVS 219, CVS 5195, Caremed, and Gulf Coast; and investigated CVS 219, CVS 5195, Caremed, and Gulf Coast. As a result of the investigations, Caremed and Gulf Coast subsequently voluntarily surrendered their DEA registrations for cause.[5]

86. Additionally, the DEA issued an AIW to the Lakeland Facility on October 26, 2011. The AIW was issued to allow the DEA to "determine whether Cardinal Health has failed to report suspicious orders to DEA as required by 21 U.S.C. § 827(d)(1) and 21 CFR § 1301.74(b)." As set forth in an affidavit in support of the AIW, "[i]n view of the foregoing circumstances the current inspection is necessary for the purpose of protecting the public health and safety. Sales of oxycodone by Cardinal Health represent an unusually large quantity of narcotic controlled substances to the average retail pharmacy." Cardinal Health produced documents to the DEA in response to the AIW.

87. Subsequently, on November 8, 2011, the DEA issued an administrative subpoena to Cardinal Health for information regarding its sales of oxycodone and other drugs, as well as its compliance mechanisms.

88. As detailed in the Rannazzisi Declaration, based on the DEA's review of the documents produced by Cardinal Health, "the investigation at Cardinal Lakeland revealed a persistent failure to exercise due diligence to ensure that controlled substances were not being diverted." The DEA concluded that, "*over a period of approximately 3 years, November 2008 to December 2011*, Cardinal's anti-diversion controls were inadequate to meet their due diligence responsibilities." (Emphasis added). This conclusion was based on, among other things,

[5] CVS 219 and CVS 5195 had their DEA registrations involuntarily revoked effective November 13, 2012. 77 Fed. Reg. 62316 (Oct. 12, 2012).

"evidence that *Cardinal's due diligence practices were inconsistent with both the 2008 MOA and Cardinal's own policies* the purpose of which was to reduce diversion." (Emphasis added). During this time period, Cardinal Health's top four Florida retailers were supplied approximately fifty times the amount of oxycodone compared to the average Florida retailer that Cardinal Health serviced.

89. As set forth in the Rannazzisi Declaration, Cardinal Health, among other things:

- Regularly exceeded the distribution thresholds it established for itself. From April 2009 to August 2011, Cardinal Health disregarded its own oxycodone thresholds for its top four Florida retailers at least forty-four times, at times by up to tens of thousands of pills.

- Failed to follow its own suspicious order monitoring policies, which required a customer site visit to investigate potential diversion once Cardinal Health attached a "red flag" to a particular customer. A number of sales should have triggered a "red flag" under Cardinal Health's operating procedures.

- Failed to conduct site visits for its retail chain pharmacy customers, thus failing to maintain effective controls to prevent diversion of controlled substances. A number of indicators of diversion could have been ascertained by conducting a site visit.

- Reported only low numbers of suspicious orders (failing almost altogether to report any suspicious orders at CVS 219, CVS 5195, Caremed, and Gulf Coast – only reporting *two* suspicious orders with respect to CVS 219, which occurred after the issuance of the AIW) and continued to sell controlled substances to certain customers after allegedly terminating those customers.

90. Details regarding the DEA's investigations are also set forth in the declaration of Ruth A. Carter, a DEA Group Supervisor who served as the lead case agent assigned to the Lakeland Facility investigation, which was submitted in support of the Opposition Brief (the "Carter Declaration," attached hereto as Exhibit 7).[6]

[6] The facts set forth in the Carter Declaration are incorporated herein by reference.

91. According to the Carter Declaration, with respect to CVS 219:

- Had Cardinal Health conducted a site visit, it would have learned that, between January 1, 2010 and October 18, 2011, forty-two percent of oxycodone sales were in cash, which is an indicator of potential diversion under Cardinal Health's own policy, "Potential Indicators of Diversion." Fewer than seven percent of patients nationwide paid for their prescriptions with cash in 2010.

- Cardinal Health increased its monthly oxycodone distributions by approximately 832 percent from 2008 to 2009, and by sixty-three percent from 2009 to 2010. Moreover, CVS 219 purchased 1,802,100 dosage units from Cardinal Health in 2011. These amounts surpassed the amount of the drug purchased by Cardinal Health's own pharmacies and in the State of Florida.

- Cardinal Health adjusted its monthly allowance threshold for oxycodone sales five times between November 25, 2009 and November 24, 2010, allowing CVS 219's monthly allowance of dosage units to increase from 112,000 to 319,000 per month.

- Although Cardinal Health held sixty-eight shipments for further inquiry, fifty-three of those shipments were ultimately released (and of the fifteen withheld, eleven were duplicate orders).

- Cardinal Health only reported two suspicious orders to the DEA, and these were only reported *after* receiving the AIW.

- Cardinal Health never sent investigators to visit CVS 219.

- Cardinal Health's failure to conduct a site visit evidenced its failure to "maintain effective controls against diversion," as required under the CSA.

92. The Carter Declaration specifically outlined "what Cardinal knew or should have known" with respect to CVS 219, outlining numerous facts and concluding that, "[h]ad Cardinal conducted appropriate due diligence, there is reason to believe that it would have known that sales to CVS 219 posed a risk of diversion for illicit use." Among other things:

- A site visit to CVS 219 would have revealed that a significant portion of the pharmacy's oxycodone customers were not using the drug for legitimate purposes. For example, during an October 2011 DEA visit to CVS 219, the "pharmacist in charge" told the

DEA that "customers often requested certain brands of oxycodone using street slang" and "30 mg oxycodone was the pharmacy's fastest moving controlled substance." Moreover, "approximately every third car that came through the drive-thru lane had prescriptions for oxycodone or hydrocodone."

- Despite the high volume of oxycodone and exponentially increasing orders, Cardinal Health never conducted a site visit that examined CVS 219's practices or procedures, choosing instead to rely on the pharmacy's own internal controls.

- Based on the DEA's review of Cardinal Health's files, the Company failed to investigate the practices at CVS 219.

93. Moreover, according to the Carter Declaration, with respect to CVS 5195:

- Had Cardinal Health conducted a site visit, it would have learned that fifty-eight percent of oxycodone sales were in cash between January 1, 2010 and October 18, 2011.

- Cardinal Health increased its monthly oxycodone distributions by approximately 793 percent from 2008 to 2009, and by 748 percent from 2009 to 2010. Moreover, CVS 5195 purchased 1,210,400 dosage units from Cardinal Health in 2011. These amounts surpassed the amount of the drug purchased by Cardinal Health's own pharmacies and in the State of Florida.

- Cardinal Health adjusted its monthly allowance threshold for oxycodone sales four times between August 11, 2010 and November 24, 2010, allowing CVS 5195's monthly allowance of dosage units to increase from 27,000 to 177,700 dosage units.

- Although Cardinal Health held twenty-two shipments for further inquiry, all of those shipments were ultimately released.

- Cardinal Health did not make any suspicious order reports to the DEA regarding CVS 5195.

- Cardinal Health never had investigators conduct a site visit of CVS 5195.

- Cardinal Health's failure to conduct a site visit evidenced its failure to "maintain effective controls against diversion," as required under the CSA.

94. The Carter Declaration specifically described "what Cardinal knew or should have known" with respect to CVS 5195, outlining a number of facts and concluding that, "[h]ad Cardinal conducted appropriate due diligence, there is reason to believe that it would have known that sales to CVS 5195 posed a risk of diversion for illicit use." Among other things:

- During a DEA visit to the pharmacy, the pharmacist in charge explained that she "set a daily limit on the number of oxycodone 30 milligram prescriptions the pharmacy would fill each day. She put the limit in place because, among other reasons, she wanted to ensure that the pharmacy had enough oxycodone 30 milligram to fill the prescriptions for 'real pain patients.'" The same pharmacist "described the pharmacy's oxycodone customers as 'shady' and admitted that some of the prescriptions were probably not legitimate."

- Despite the high volume of oxycodone and exponentially increasing orders, Cardinal Health never conducted a site visit that examined CVS 5195's practices or procedures, choosing instead to rely on the pharmacy's internal controls.

- Based on the DEA's review of Cardinal Health's files, the Company failed to investigate the practices at CVS 5195.

95. According to the Carter Declaration, with respect to Gulf Coast:

- Forty percent of oxycodone sales were in cash as of April 30, 2009.

- Cardinal Health increased its monthly oxycodone distributions by approximately 549 percent from 2008 to 2009, and by 404 percent from 2009 to 2010. Moreover, Gulf Coast purchased 2,063,100 dosage units from Cardinal Health in 2011. These amounts surpassed the amount of the drug purchased by Cardinal Health's own pharmacies and in the State of Florida.

- Cardinal Health adjusted its monthly allowance threshold for oxycodone sales eleven times between April 13, 2009 and May 26, 2010, allowing Gulf Coast's monthly allowance of dosage units to increase from 20,000 to 314,400.

- Although Cardinal Health held sixty-one shipments for further inquiry, fifty-two of those shipments were ultimately released, and of the nine orders not shipped, almost half were duplicate orders.

- Cardinal Health did not make any suspicious order reports to the DEA regarding Gulf Coast.

- Cardinal Health conducted five site visits to Gulf Coast between August 2008 and February 2011. One of those visits resulted in an assessment of "High Risk of Diversion." A second visit resulted in an assessment of "Medium Risk of Diversion." Nevertheless, Cardinal Health did not contact the DEA regarding these findings, and indeed, shortly after reaching these conclusions, substantially *increased* its monthly volumes of oxycodone to Gulf Coast. The "High Risk of Diversion" assessment was made on October 5, 2011. The report from the site visit indicated, "I have requested permission to contact DEA to resolve this issue." However, Cardinal Health did not contact the DEA, and on November 24, 2010, the Company adjusted its monthly volumes of oxycodone to Gulf Coast from 141,000 to 207,200. Moreover, the "Medium Risk of Diversion" assessment was made on February 17, 2011. Nevertheless, Cardinal Health increased Gulf Coast's order threshold from 207,200 to 245,000 on April 26, 2011; from 245,000 to 265,000 on April 27, 2011; and from 265,000 to 317,000 on May 26, 2011. These increases constituted a sixty-five percent increase in Cardinal Health's authorized shipment volumes of oxycodone.

- On November 4, 2011, Gulf Coast voluntarily surrendered its DEA registration for cause.

96. According to the Carter Declaration, with respect to Caremed:

- Forty percent of oxycodone sales were in cash as of September 21, 2011.

- Cardinal Health increased its monthly oxycodone distributions by approximately 1020 percent from 2008 to 2009, and by 213 percent from 2009 to 2010. Moreover, Caremed purchased 1.1 million dosage units from Cardinal Health in 2011. These amounts surpassed the amount of the drug purchased by Cardinal Health's own pharmacies and in the State of Florida.

- Cardinal Health adjusted its monthly allowance threshold for oxycodone sales nine times between April 14, 2010 and May 26, 2011, allowing Caremed's monthly allowance of dosage units to increase from 26,000 to 158,300 dosage units.

- Although Cardinal Health held fifty-four shipments for further inquiry, forty-seven of those shipments were ultimately released, and of the seven orders Cardinal Health did not ship, three were duplicate orders.

- Cardinal Health did not make any suspicious order reports to the DEA regarding Caremed.

- In response to the AIW, Cardinal Health conducted three site visits to Caremed between May 4, 2010 and September 21, 2011. After one of these investigations, a Cardinal Health employee recommended that the Company hold oxycodone shipments to Caremed at their current volume. Nevertheless, Cardinal Health increased the orders two times in the following four months, constituting a fifty-seven percent increase. The third site visit resulted in a conclusion of "High Risk of Diversion."

- Caremed voluntarily surrendered its DEA registration for cause on October 18, 2011.

97. Based on its investigations, the DEA issued the 2012 ISO regarding the Lakeland Facility on February 2, 2012. The 2012 ISO provided that "[d]espite the MOA, the specific guidance provided to Cardinal by DEA, and despite the public information readily available regarding the oxycodone epidemic in Florida, Cardinal has failed to maintain effective controls against the diversion of controlled substances into other than legitimate medical, scientific, and industrial channels, in violation of 21 U.S.C. §§ 823(b)(1) and (e)(1)."

98. The 2012 ISO stated that "[s]ince at least 2009, Cardinal's largest purchasers of oxycodone products have been retail pharmacies in the State of Florida engaged in a scheme to distribute controlled substances based on purported prescriptions that were issued for other than a legitimate medical purpose and outside the usual course of professional practice."

99. According to the 2012 ISO, from January 1, 2008 to December 31, 2011, Cardinal Health's sales of oxycodone products to its top four retail pharmacy customers exceeded 12.9 million dosage units, and the "egregious quantities of oxycodone distributed by Cardinal to its

top four retail pharmacy customers well exceeded the amount of oxycodone distributed to Cardinal's Florida retail pharmacies[.]" Specifically, from January 1, 2008 to December 31, 2011, Cardinal Health sold: (i) over 5 million dosage units of oxycodone to its top customer, CVS 219; (ii) approximately 3.4 million dosage units of oxycodone to Gulf Coast; (iii) approximately 2.2 million dosage units of oxycodone to CVS 5195; and (iv) approximately 2.1 million dosage units of oxycodone to Caremed. The volumes of oxycodone in dosage units shipped to these customers is summarized in the chart below:

Customer	2008 Volume	2009 Volume	2010 Volume	2011 Volume	2009 to 2011 Percentage Change	Total
CVS 219	135,000	1,258,600	2,048,100	1,802,100	43%	5,243,800
CVS 5195	11,700	104,500	885,900	1,210,400	1058%	2,212,500
Gulf Coast	32,820	213,100	1,073,540	2,063,100	868%	3,382,560
Caremed	20,700	231,740	724,500	1,097,300	374%	2,074,240
Total Per Year	200,220	1,807,940	4,732,040	6,172,900	241%	12,913,100

100. The 2012 ISO stated that, "[n]otwithstanding the large quantities of controlled substances ordered by Cardinal's top retail pharmacy customers, Cardinal failed to conduct meaningful due diligence to ensure that the controlled substances were not diverted into other than legitimate channels, including Cardinal's failure to conduct due diligence of its retail pharmacy chain customers." The ISO continued: "Cardinal failed to detect and report suspicious orders of oxycodone products by its pharmacy customers, as required by 21 C.F.R. § 1301.74(b). In addition, Cardinal's conduct described herein violated the provisions of the Administrative Memorandum of Agreement."

101. As set forth in the 2012 ISO, "Cardinal's continued registration is inconsistent with the public interest[,]" and "continued registration while the[] proceedings are pending constitutes an imminent danger to the public health and safety."

102. According to the declaration of Michele M. Leonhart, Administrator of the DEA and issuer of the four ISOs discussed herein, which was submitted in support of the Opposition Brief (the "Leonhart Declaration," attached hereto as Exhibit 8),[7] "Cardinal's prior compliance problems, particularly those at Cardinal Lakeland, played a significant role in my conclusion to issue the February 2, 2012 ISO. I found that Cardinal Lakeland had failed to maintain adequate diversion controls, had violated the terms of its 2008 MOA, and posed an imminent danger to public health and safety."

103. Under a section of her declaration titled "Cardinal's History of Inadequate Controls Against Unlawful Diversion," Leonhart explained, among other things:

> Between November 28, 2007, and December 7, 2007, I issued ISOs suspending distributions at three Cardinal facilities – including Cardinal Lakeland. At the time, I concluded that the three facilities posed an imminent danger to public health or safety based on a DEA investigation revealing that Cardinal Lakeland "failed to maintain effective controls against diversion." On January 30, 2008, DEA also issued an Order to Show Cause to revoke the registration of Cardinal's Stafford, Texas facility based on the failure to maintain effective controls against diversion. . . .
>
> In addition to the four Cardinal distribution facilities described above, I also had reason to conclude that Cardinal "failed to maintain effective controls against the diversion of controlled substances" at three other facilities.
>
> On September 30, 2008, Cardinal entered into an Administrative Memorandum of Agreement (MOA) with DEA. I approved the terms of the 2008 MOA between Cardinal and DEA. The purpose of the 2008 MOA was to establish mechanisms to ensure all Cardinal distribution facilities comply with the CSA.

(Citations omitted).

104. The Leonhart Declaration continued:

> DEA's recent investigation indicated that Cardinal Lakeland had been distributing excessive quantities of oxycodone to its top Florida retail pharmacy customers. DEA previously suspended Cardinal Lakeland because of its failure to maintain adequate safeguards against diversion, a conclusion DEA reached after an

[7] The facts set forth in the Leonhart Declaration are incorporated herein by reference.

> investigation into Cardinal Lakeland's distribution of hydrocodone to internet pharmacies. *Although the drugs and the end customers were different, the common thread was Cardinal Lakeland's inadequate anti-diversion measures. The results of the recent investigation strongly indicated to me that, contrary to its promises in the 2008 MOA, Cardinal had not maintained adequate anti-diversion measures at its Lakeland facility*.

(Emphasis added).

105. According to Leonhart, "Cardinal Lakeland sold high volumes of oxycodone to these CVS stores despite all the warning signs, leading me to conclude that Cardinal's Lakeland facility had failed in its obligation to identify, report, and act upon the suspicious nature of the orders placed by these stores. This failure violated the terms of the MOA and the CSA." Furthermore,

> *Cardinal Lakeland was on notice of its obligation to maintain adequate anti-diversion controls*. DEA advised Cardinal Lakeland of its obligations through the MOA and through ongoing communications with Cardinal Lakeland, in which it provided guidance concerning warning signs that could indicate ongoing diversion. Nevertheless, Cardinal Lakeland continued to supply these customers despite clear warning signs. . . . [H]ad Cardinal Lakeland taken basic steps to investigate their activities, it would have detected serious problems with its top four customers.

(Emphasis added). Moreover, "the disturbing pattern of sales to all four pharmacies over an extended time period gave me reason to believe that Cardinal Lakeland did not have adequate anti-diversion controls in place with regard to its sales to its more than 5,200 other retail customers."

106. On February 3, 2012, Cardinal Health filed a complaint and an application for a temporary restraining order ("TRO") with respect to the 2012 ISO. *Cardinal Health, Inc. v. Holder*, Case No. 1:12-cv-00185 (D.D.C.). After a hearing on February 3, 2012, at which counsel for the government was not present, the Court granted Cardinal Health's request for a TRO. Cardinal Health subsequently filed a Motion for Preliminary Injunction on February 6,

2012, which the Court denied on February 29, 2012. The Company filed a notice of appeal on February 29, 2012, and filed an emergency motion for injunction pending appeal on March 2, 2012, which was denied on March 16, 2012.

107. On May 15, 2012, Cardinal Health announced that it agreed to a settlement with the DEA to resolve the ongoing litigation with respect to the 2012 ISO. Pursuant to the settlement, Cardinal Health agreed to a two-year suspension of the Lakeland Facility's DEA registration to ship controlled medicines from the facility. Cardinal Health also agreed, as it did in 2008, to improve its anti-diversion procedures.

E. ***Cardinal Health's New York Diversion Compliance Settlement Agreement***

108. On December 26, 2006, the New York State Attorney General's Office ("OAG") issued a press release announcing an agreement with Cardinal Health "to improve the safety and security of practices in the trading of prescription pharmaceuticals among wholesalers."

109. According to the press release:

> An investigation by the Attorney General's Office into the trading of pharmaceuticals on the "secondary market" determined that certain trading practices by wholesalers had the potential to compromise the security and safety of the national drug distribution system.
>
> * * *
>
> In today's settlement, Cardinal has agreed to adopt a set of Wholesaler Safe Product Practices that establish a new standard for the safe trading of pharmaceuticals and point the way forward for an industry that is vital to the health of Americans.
>
> The investigation, which began in 2005 and is continuing with regard to other wholesalers, concerns trading practices in the secondary market for prescription pharmaceuticals. That is the market in which wholesalers trade drugs among themselves, after the drugs are sold by the manufacturer but before they are purchased by a pharmacy, hospital, or other end user. The wholesalers who sell drugs to other wholesalers are called alternate source vendors.

Secondary market trading is not illegal on its face, but can create opportunities for the introduction of unreliable drugs, including counterfeits, into the marketplace. In recent years, there has been an increase in the number of cases of counterfeit drugs in the American supply chain. *Secondary market trading also can create an opportunity for companies to divert drugs from their intended distribution channels*. Diversion into the secondary market, often to take improper advantage of manufacturer discounts, can begin a series of trades from wholesaler to wholesaler that makes it difficult to trace the origin of a drug and impossible to ascertain its authenticity.

The investigation determined that Cardinal purchased drugs from certain alternate source vendors, despite risks associated with buying from those vendors, to take advantage of higher available profit margins. Cardinal also sold pharmaceuticals to certain customers even in the face of evidence that those customers may have been illegally diverting the drugs outside their intended channels of distribution.

Under the terms of today's settlement, Cardinal will adopt an innovative set of Wholesaler Safe Product Practices, and has agreed that it will not sell pharmaceuticals to another wholesaler unless that wholesaler also adopts that same set of practices. The Wholesaler Safe Product Practices are designed to ensure that a drug may not pass through the hands of more than two wholesalers after the manufacturer sells it and before it is bought by a pharmacy or other end user.

In addition to adopting the Wholesaler Safe Product Practices, Cardinal has agreed that in the regular course of its business it will:

- Buy pharmaceuticals directly from manufacturers and not on the secondary market from alternate source vendors;

- Sell pharmaceuticals only to wholesalers who have certified their compliance with the Wholesaler Safe Product Practices, and have agreed to allow audits of those certifications;

- Adopt "know your customer" provisions and monitor for customer diversion; and Hire an external auditor to conduct periodic reviews of its compliance with the settlement.

Cardinal will also pay $7 million to Health Research Inc., a New York not-for-profit corporation affiliated with the New York State Department of Health and the Roswell Park Cancer Institute, and an additional $3 million to the state of New York.

http://www.ag.ny.gov/press-release/state-reaches-agreement-cardinal-drug-trading-issues (emphasis added). The settlement referred to above also required the Company to pay $1 million to the OAG to cover costs of its investigation.

110. The settlement referred to in the press release, entitled "Assurance of Discontinuance Pursuant to Executive Law §63(15)" (the "Discontinuance") stated, among other things, that "[i]n a 2003 internal Cardinal e-mail *to a compliance officer*, one executive addressed the issue of 'smaller vendors' which provided 'unique opportunities' to Cardinal. Although acknowledging that the vendors are 'high risk,' the writer concluded that '*[s]ince we need the margin from these high risk vendors we will continue to buy from them*.'" Exhibit 9, attached hereto (emphasis added).

111. The Company's failure to adopt adequate procedures and safeguards to prevent drug diversion when dealing in secondary market trading had results such as the following, as set forth in the Discontinuance:

> 11. Cardinal repeatedly sold pharmaceuticals to customers that it knew or should have known were diverting pharmaceuticals. Prior to March 2005, Cardinal made numerous sales of pharmaceuticals to a Nevada company which purported to be a "closed-door" pharmacy that served only nursing homes. In a routine pattern, the Nevada company placed two orders at the same time. One was for products likely to be needed by its stated patient population of nursing home residents, typically in quantities of ones or twos, as would be expected for its needs. The other was for much higher quantities and included products unlikely to be needed by the nursing home residents. Despite this pattern, Cardinal continued to fill the company's dual orders as described above. Investigation has shown that the company dispensed the products on the small-quantity orders to nursing home residents, and it transferred the products on the large-quantity orders to an affiliated wholesaler for resale on the Secondary Market. In March 2005, Cardinal discontinued doing business with this purported closed-door pharmacy.
>
> 12. Similarly, starting in January 2003, Cardinal was alerted that its customers in the Carrington network of closed-door pharmacies were diverting drugs. One warning came from a Cardinal sales representative who reported visiting the Carrington pharmacies and finding the doors locked, an "Administrative Assistant" on site but no pharmacist, about thirty large boxes

awaiting pickup by UPS and delivery to a wholesaler in Kentucky, and purchase orders from a Florida wholesaler with directions to ship to the Kentucky wholesaler. One of the Administrative Assistants explained in detail the process by which the closed-door pharmacy received drugs and sold them to the wholesalers. Cardinal took steps to determine whether the Carrington pharmacies were engaged in diversion, but continued its sales, though at a reduced level, until September 2003. The steps taken by Cardinal, such as seeking assurances from Carrington executives and accepting those assurances, were, in light of other evidence known to Cardinal, inadequate. In December 2003, Cardinal finally severed its business relationship with Carrington after learning from law enforcement that Carrington was under criminal investigation. . . .

13. Cardinal also sold pharmaceuticals to wholesalers who were at the same time on Cardinal's excluded vendor list – in other words, wholesalers that Cardinal itself deemed sufficiently high-risk that it adopted the policy of never buying product that had passed through their hands. The Trading Company president noted as to one wholesaler in June 2003 that "several things that have happened in the past are making us feel we need to very closely examine our buying" from the wholesaler, while simultaneously noting that "we are fine" with selling to that same wholesaler. In another example from December 2003, the president reported that "we now have been asked by compliance" to add a certain wholesaler to the excluded vendor list, but "We can still sell to them."

112. According to the Discontinuance, Cardinal Health:

- hired a Chief Ethics and Compliance Officer in the Spring of 2005 with responsibility for reviewing anti-diversion investigative reports and, in conjunction with senior management, approving any corrective action;

- promulgated an Anti-Diversion Compliance Policy, an Anti-Diversion Compliance Manual, and developed an Anti-Diversion Training Program in February 2006, and created the position of Anti-Diversion Compliance Coordinator; and

- issued a revision of the employee code of conduct that addressed the diversion of prescription pharmaceuticals.

113. The Discontinuance assigned the following responsibilities to the Chief Ethics and Compliance Officer:

- direct reporting lines to the CEO and to the Audit Committee or similar oversight committee of the Board of Directors;

- [r]eport in writing, at least once every six months, to the relevant oversight committee of the Board of Directors as to his or her activities with respect

> to Cardinal's compliance efforts under this Assurance, including actual or suspected issues, steps taken to investigate and resolve issues, and any recommendations for changes in corporate practices.

114. Despite these steps, by 2006 at the latest, Cardinal Health's distribution centers had begun engaging in massive diversions of controlled substances for improper purposes that culminated in the 2008 MOA and a $34 million civil fine.

F. *The West Virginia Litigation*

115. As stated in the Company's Form 10-Q, filed with the SEC on November 5, 2014:

> In June 2012, the West Virginia Attorney General filed, and in January 2014 amended, complaints against 13 pharmaceutical wholesale distributors, including us, in the Circuit Court of Boone County, West Virginia alleging, among other things, that the distributors failed to maintain effective controls to guard against diversion of controlled substances in West Virginia, failed to report suspicious orders of controlled substances in accordance with the West Virginia Uniform Controlled Substances Act ["WVUCSA"] and were negligent in distributing controlled substances to pharmacies that serve individuals who abuse controlled substances. In addition to injunctive and other equitable relief, the complaints seek monetary damages and the creation of a court-supervised fund, to be financed by the defendants in these actions, for a medical monitoring program focused on prescription drug abuse.

The initial West Virginia complaint was filed shortly after the Company and the DEA settled their litigation regarding the 2012 ISO.

116. More specifically, Paragraph 2 of the amended West Virginia complaint alleged that Cardinal Health:

> was on notice of the growing West Virginia epidemic from the abuse of those prescription drugs which it supplied and of the quantities and frequency with which those drugs were distributed to entities in West Virginia. Notwithstanding their knowledge and the Defendant's attendant duties as required by West Virginia law and industry customs and practices this Defendant inserted itself as an integral part of the pill mill process which fuels this epidemic.

Exhibit 10, attached hereto.

117. Paragraph 5 of the amended West Virginia complaint alleged that Cardinal Health:

> has profited from this epidemic by distributing controlled substances in West Virginia in amounts that are in excess of the amount of controlled substances legitimately medically required, thereby sourcing drugs ultimately used by drug abusers. West Virginia law requires distributors of controlled substances such as this defendant to, "provide effective controls and procedures to guard against . . . diversion of controlled substances [and] shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. . . . Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 15 WVCSR § 2-4.2.1 and 15 WVCSR § 2-4.4. By distributing excessive amounts of controlled substances, the Defendant violated West Virginia law by failing to implement or more particularly to follow and adhere to effective controls to guard against prescription drug diversion and by failing to effectively monitor, enforce and/or disclose the suspicious orders it filled.

118. Paragraph 6 of the amended West Virginia complaint alleged the Company "is aware of its legal responsibilities in regard to preventing suspicious orders of abused prescription drugs from flooding susceptible locales," citing its 2008 $34 million settlement with the DEA; the 2012 ISO settlement with the DEA; and a 2006 guilty plea in Texas to illegally distributing controlled substances from 1999 through 2005 by an internet pharmacy owner who acknowledged purchasing controlled substances from Cardinal Health.

119. Paragraphs 13 through 18 of the amended West Virginia complaint explored in detail the similarities between the circumstances in Florida leading to the 2012 ISO and "Cardinal's conduct in West Virginia," particularly "suppl[ying] controlled substances to rogue drugstores which dispense controlled substances based on bogus prescriptions from unethical physicians who are prescribing controlled substances for illegitimate medical purposes."

120. The five-count West Virginia amended complaint seeks injunctive and equitable relief, damages, civil penalties, and attorneys' fees, among other things, for violations of the Company's responsibilities and duties under the WVUCSA; negligence and violations of the

WVUCSA; violations of the West Virginia Consumer Credit and Protection Act; a public nuisance created, perpetuated, and maintained by the Company; and common law negligence.

G. *Harm to the Company*

121. As a result of its repeated disregard and violations of the CSA, state law, and applicable regulations, Cardinal Health has suffered substantial harm.

122. Due to the conduct that took place from 2005 to 2008, Cardinal Health has already paid a $34 million civil fine, which was, at the time, the largest fine in United States history associated with a DEA registration suspension. Of that $34 million fine, $16 million—a little less than half of the fine—was attributable to the conduct that took place at the Lakeland Facility. In addition, the Company paid $11 million in connection with the Discontinuance to resolve OAG's allegations regarding its secondary market trading activities that were associated with improper drug diversion.

123. Not only did the Company suffer the $34 million fine, but according to Giacomin,[8] after the 2007 ISOs, "[m]any of Cardinal Health's customers relayed their concerns . . . about the disruptions in service they experienced as a result of those ISOs. . . . [M]any of those customers left Cardinal Health and have not returned." Exhibit 3, ¶ 3.

124. Moreover, "Cardinal Health suffered significant revenue losses as a result of the December 5, 2007 suspension of the Lakeland facility." Exhibit 11, ¶ 3, attached hereto. Giacomin explained that delays in shipments due to the ISO "caused some customers to leave Cardinal Health for other distributors." *Id*. On August 7, 2008, Demand and Diversion

[8] Cardinal Health submitted three Giacomin declarations (the "Giacomin Declarations") in *Cardinal Health, Inc. v. Holder*. The first declaration was submitted on February 3, 2012, in connection with the Company's application for a TRO. The other declarations were submitted on February 6, 2012 and February 13, 2012, in connection with the Company's Motion for Preliminary Injunction.

Defendant Barrett, now Cardinal Health's CEO and Chairman, publicly disclosed to investors on an earnings call that, at that time, "Cardinal Health estimated that the suspensions of the Lakeland, Auburn, Swedesboro, and Stafford facilities, and related remedial measures, had *caused Cardinal Health to lose 'roughly $1 billion of lost sales' on an annualized basis*." (Emphasis added).

125. According to Giacomin, as a result of the 2007 ISO, some customers who stayed with Cardinal Health decreased the amounts of purchases they made from the Company and increased purchases from other suppliers, and even after the Lakeland Facility resumed shipping in October 2008, "average purchases by the remaining customers remained depressed." Exhibit 11, ¶ 4. The Company estimated that "*just one portion of these losses*—decreased sales to retail independent pharmacies that remained with Cardinal Health—*amounted to approximately $100 million*." *Id*. (Emphasis added).

126. According to a May 10, 2012 *Bloomberg* article entitled "Cardinal Health Set for DEA Showdown Over Painkiller Sales Ban," "[f]rom the DEA's first facility suspension on Nov. 28, 2007, to Oct. 29, 2008, when the company reported first-quarter earnings after settling with the agency, Cardinal shares fell 40 percent to $25.21 from $42.26."

127. With respect to the 2012 ISO, the Giacomin Declarations provide that "[t]he rerouting of controlled substances to other distribution centers [other than the Lakeland Facility] will require Cardinal Health to expend substantial effort and resources." Exhibit 3, ¶ 7. Moreover, "[i]t is anticipated that some of Cardinal Health's Florida customers experiencing service delays will leave Cardinal Health for other distributers and Cardinal Health's business reputation will be significantly tarnished as customers come to view Cardinal Health as unreliable. . . . [T]hese customers will take their entire pharmaceutical business away from

Cardinal Health. Their perceptions of Cardinal Health's reliability, moreover, may carry over to potential customers as well." *Id*. ¶ 20.

128. Giacomin also expressed that "[t]he inability to distribute pharmaceuticals in the Florida market could have severe consequences for Cardinal Health's entire pharmaceutical business. Indeed, many national chain customers, who cannot receive timely shipments for their controlled substances in Florida, will choose to take their national accounts to other distributors. As a result, DEA's ISO poses a risk to Cardinal Health's national business in pharmaceuticals." *Id*. ¶ 21. The Company anticipated that the "delays will cause some of Cardinal Health's customers to leave Cardinal Health permanently for other distributors, as occurred following the 2007 ISO of the Lakeland facility. These harms cannot later be cured." *Id*. ¶ 22.

129. Giacomin concluded that "[i]t is likely that an ISO of the Lakeland distribution center today *would have an even greater impact than the December 5, 2007 ISO did*. During the period in which the Lakeland facility's registration was suspended as a result of the December 5, 2007 ISO, Cardinal Health's principal competitors, McKesson and AmerisourceBergen, faced disruptions in their distributions to Florida as well. Absent those disruptions, the losses to Cardinal Health as a result of the December 5, 2007 ISO likely would have been even greater." (Emphasis added). Exhibit 11, ¶ 5.

130. According to a May 15, 2012 article in *The Wall Street Journal*, "Cardinal has said that shipping the controlled medicines from longer distances—and the legal costs associated with the DEA case—added about $4 million in costs during its most recent quarter."

131. The settlement with DEA did not end the Company's potential liability arising from the events culminating in the 2012 ISO. The Company has stated in various SEC filings that "[t]he settlement agreement did not foreclose the possibility of the [DOJ] seeking civil fines

in Florida or elsewhere for the conduct covered by the settlement agreement. In that regard, we are continuing to provide information to and engage in discussions with several offices of the DOJ, including preliminary discussions regarding the feasibility of a settlement, and have accrued $27 million for this matter."

132. As a result of the 2012 ISO, the Company has and will continue to suffer significant harm and incur substantial costs, including potential fines, attorneys' fees, loss of business, and reputational harm.

133. In addition, the Company has and will continue to suffer significant harm and incur substantial costs, including attorneys' fees, defending the West Virginia litigation, and is faced with the prospect of injunctive relief and substantial monetary liability under West Virginia Uniform Controlled Substances Act and treble damages under the West Virginia Antitrust Act, among others.

V. DERIVATIVE ALLEGATIONS

134. Plaintiff incorporates by reference all preceding and subsequent paragraphs as if fully set forth herein.

135. Plaintiff brings this action derivatively in the right and for the benefit of the Company to redress injuries suffered and to be suffered by the Company because of the breaches of fiduciary duties by the Defendants.

136. Plaintiff will adequately and fairly represent the interests of the Company in enforcing and prosecuting its rights, and has retained counsel experienced in litigating actions of this type.

137. Plaintiff is an owner of Cardinal Health stock and was an owner of Cardinal Health stock at all times relevant to the Defendants' wrongful conduct alleged herein.

VI. DEMAND WAS WRONGFULLY DENIED

138. Plaintiff incorporates by reference all preceding and subsequent paragraphs as if fully set forth herein.

139. The basic authority of directors to terminate shareholder derivative litigation is governed by applicable state law unless that law is inconsistent with the federal policies on which the litigation is based. Cardinal Health is incorporated in Ohio and, thus, Ohio corporation law governs the issue of whether Plaintiff's demand on the Board was properly considered and denied.

140. Under Ohio law, a board of directors, through a special committee, may decide whether it is in the best interest of the company to pursue or terminate litigation filed on its behalf. However, there is no presumption in favor of the good faith of a special committee. A court will not defer to a Board's decision not to pursue a derivative action against itself pursuant to a shareholder demand unless: (1) the special committee is comprised of independent, disinterested trustees; (2) the special committee conducts its inquiry in good faith; and (3) the committee's recommendation is the product of a thorough investigation.

141. By letter dated September 5, 2013, following the affirmance of the dismissal of his complaint by the Sixth Circuit, counsel for the plaintiff in *Stanley*[9] made a demand on the Board that it "immediately investigate and commence legal action for remedial and other relief against" the Diversion Defendants "for violating their fiduciary duties in connection with the allegations contained in the Verified Complaint filed by Mr. Stanley in the case captioned *Stanley* v. *Arnold*, Case No. 1:12-cv-00482." The letter continued:

> As a result of the misconduct detailed in the Complaint, the Company has suffered substantial financial injuries detailed in the Complaint, which have not

[9] Counsel for Stanley is now counsel for Erste.

> been remediated. These damages and injuries to the Company occurred on the Director Defendants' watch and as a direct and proximate result of their failure to take steps to ensure satisfactory performance of its duties.
>
> As you are aware, the Sixth Circuit Court of Appeals upheld the dismissal of Mr. Stanley's action in an unpublished Order based upon his failure to adequately plead demand futility under applicable Ohio law. In light of that ruling, Mr. Stanley now demands that the Company investigate his claims and bring appropriate action against the Director Defendants.
>
> In making the foregoing demands to investigate and commence litigation, our client does not concede in any way that the current board of the Company or any member thereof is disinterested, independent, or competent to consider these demands.
>
> It is incumbent on the current board to hold accountable all those responsible for the harm done to the Company. We look forward to your prompt reply acknowledging receipt of this formal demand and setting forth the remedial steps that the board has taken and will take to vindicate the rights of the Company against the persons responsible for the wrongdoing alleged.

Exhibit 12, attached hereto.

142. By letter dated September 12, 2013, Falk replied:

> The members of the Board are being advised of your communication. As you are presumably aware, a special committee of the Board was constituted in connection with an earlier shareholder demand letter. Your communication has been transmitted to that committee.
>
> At the moment, it is not possible to gauge timing of any updates concerning the Board or special committee's consideration of your letter. However, our Board's next scheduled meeting is in November, and, as such, it is possible that an update may be available following that meeting.

Exhibit 13, attached hereto.

143. By letter dated October 23, 2013, counsel for Stanley wrote to counsel for the special committee to request certain critical information about the special committee and to bring certain events to the committee's attention. The letter stated:

> *The Company's response to the Demand did not identify the members of the Special Committee in connection with the prior demand or the current Demand. Please provide that information to me.* In addition, during our call on October 21, 2013, you mentioned that the Special Committee had prepared a

report in connection with the earlier stockholder demand referenced in the Company's September 12, 2013 response letter. *Please provide a copy of that report and any exhibits thereto. We are willing to enter into a reasonable, mutually acceptable confidentiality agreement to facilitate the production of the report.* In addition, the Company's response letter asked that we provide proof of Mr. Stanley's continuing ownership interest in the Company. We will provide that information upon execution of a confidentiality agreement.

In addition, during our call on October 21, 2013, you asked whether we had additional information not contained in the Complaint that we wished to bring to the attention of the Special Committee.

I initially informed you that we did not. However, after reviewing the file, there are additional material facts not included in the pleadings that we believe the Special Committee should investigate.

First, in [sic] on December 26, 2006, the Company entered into a civil settlement with the Attorney General's Office of the State of New York and paid a fine of $11 million. Paragraphs 11-13 of the settlement agreement, titled Assurance of Discontinuance Pursuant to Executive Law §63(15) (the "Settlement Agreement"), reference, among other things, that the Company "repeatedly sold pharmaceuticals to customers that it knew or should have known were diverting pharmaceuticals."

Paragraph 16 of the Settlement Agreement states that the Company "promulgated an Anti-Diversion Compliance Policy, an Anti-Diversion Compliance Manual, and Developed an Anti-Diversion Training Manual." Paragraph 16 of the Settlement Agreement also states that the Company "created the position of Anti-Diversion Compliance Coordinator." Paragraph 17 of the Settlement Agreement states that the Company "issued a revision of the employee code of conduct that addressed the diversion of prescription pharmaceuticals" and that the "Chief Ethics and Compliance Officer has the responsibility for reviewing anti-diversion investigative reports, and in conjunction with senior management, approving any corrective action."

We believe that the Special Committee should investigate the extent to which the Director Defendants approved or otherwise were informed about the Settlement Agreement. The Special Committee should also investigate whether the Director Defendants received any information regarding the Company's compliance with the Settlement Agreement including, at a minimum, whether they received any reports from the Company's Chief Ethics and Compliance Officer regarding the diversion of pharmaceuticals. The Special Committee should also investigate whether, if at all, the Director Defendants received any reports regarding the efficacy of the Company's anti-diversion compliance measures adopted in connection with the Settlement Agreement.

Second, the Company's Form 10-K for the fiscal year ended June 30, 2008, which was filed with the SEC on August 27, 2008, a month before the Memorandum of Agreement ("MOA") was executed, and was signed by Director Defendants Arnold, Darden, Finn, Kenny, Notebaert, Raisbeck, and Spaulding, said the following about the 2007 Immediate Suspension Orders ("ISO"), the 2008 Order to Show Cause, and the impending MOA and fine:

> Settlement discussions have recently commenced with the DEA regarding resolution of this matter. On August 7, 2008, the Company and the DEA staff reached an oral agreement in principle to resolve the license suspensions. The oral agreement is subject to the completion of definitive documentation as well as approval by the DEA Administrator and the U.S Department of Justice. As a result of these developments, the Company recorded a reserve of $34.0 million for its quarter ended June 30, 2008 for this matter. The Company expects that the license suspensions will be lifted during the quarter ending December 31, 2008. There can be no assurance, however, that the Company's efforts to resolve the DEA matter will be successful within the expected timeframe or will be successful at all, and the Company cannot predict the final terms of any settlement.

http://www.sec.gov/Archives/edgaridatal721371/000119312508184519/dlOk.htm, at 101, 134-35. Mr. Stanley referenced this language in his Appeal Briefs. Plaintiff referenced this language in his Reply Brief. We believe that in light of the Company's statements, the Special Committee should investigate the Director Defendants' knowledge regarding the ultimate settlement with the U.S. Drug Enforcement Administration ("DEA"), and any efforts the Director Defendants made to ensure that the Company was in compliance with that settlement.

Third, on June 26, 2012, the Attorney General for West Virginia filed a complaint against the Company based upon the 2012 ISO. West Virginia ex reI. McGraw v. Cardinal Health, Inc., C.A. No. 12-C-140 (W.Va. Boone Cnty. Cir. Ct.). The lawsuit is not cited in the Complaint but it was referenced in Mr. Stanley's brief in opposition to the motion to dismiss and well as in his appellate brief. The West Virginia lawsuit seeks to recover the costs caused by the prescription painkiller abuse epidemic fueled by Cardinal Health's supply in West Virginia of "controlled substances to rogue drugstores which dispense controlled substances based on bogus prescriptions from unethical physicians who are prescribing controlled substances for illegitimate medical purposes." Paragraph 19 of the West Virginia complaint alleges that the Company did not consistently report suspicious orders to the West Virginia Board of Pharmacy and "has failed to diligently respond to the suspicious orders which [the Company] has filled. The [Company] therefore has failed to provide effective controls and procedures to guard against diversion of controlled substances in contravention of West Virginia law." We believe that the Special Committee should investigate the Company's alleged failure to report suspicious orders in West Virginia and determine whether

> the Director Defendants were aware of any issues regarding the selling, marketing, or reporting of controlled substances in West Virginia.
>
> Please be advised that it making these facts known to the Special Committee, Mr. Stanley does not concede in any way that the current board of the Company or any member thereof is disinterested, independent.
>
> As set forth in Mr. Stanley's Demand, it is incumbent on the current board to hold accountable all those responsible for the harm done to the Company.
>
> We look forward to your prompt reply to this letter *including our request for any Special Committee report regarding the previously made demand. Should you have any requests, questions, or concerns, please do not hesitate to contact us. We would appreciate an opportunity to meet with the Special Committee and/or its representatives before it reaches any final conclusions regarding any investigation it decides to conduct*.

Exhibit 14, attached hereto (emphasis added, brackets in original).

144. By letter dated February 6, 2014, Falk wrote to counsel for Stanley and advised that the Board had rejected Stanley's demand. The letter stated:

> As you know from previous communications and from Cardinal Health's public filings, a special committee of the Cardinal Health Board of Directors had previously been appointed to investigate matters set forth in an earlier, similar shareholder demand. Upon receiving the committee's findings and recommendations, the Board determined to reject that earlier demand as not being in the best interest of the Company. That action was taken and publicly disclosed by the Company prior to receipt of your October 23, 2013 letter. Your Demand Correspondence was referred to the same committee.
>
> In connection with its work regarding the earlier demand and the additional work that followed receipt of the Demand Correspondence, the committee conducted an extensive investigation with the assistance of independent counsel (Milbank, Tweed, Hadley & McCloy LLP), including review of over 15,000 pages of relevant material and interviews of 26 witnesses, plus an interview with counsel for the shareholder in the earlier demand and conversations with you. At the conclusion of its investigation, the special committee informed the Board that, based on the factual information the committee had gathered during the overall investigation and applicable law, it had concluded that it would not be in the best interest of the Company to pursue claims for breach of fiduciary duty against the persons named in the Demand Correspondence. Accordingly, the committee recommended that the Board not pursue the action requested by the Demand Correspondence.

> At its meeting on February 4, 2014, the full Board considered the results of the special committee's investigation and its recommendations. After substantial discussion and deliberation, including consideration of the earlier work of the special committee, the Board determined to accept the special committee's report and to adopt the committee's recommendation. Accordingly, the Board has determined to reject the demand set forth in the Demand Correspondence, and the purpose of this letter is to advise you of that determination.

Exhibit 15, attached hereto.

144. The Company did not identify the members of the special committee for either the prior or current demands, as requested by Stanley; Plaintiff in the instant action learned their names through Company SEC filings. The Company did not provide Stanley with a copy of the special committee's report and recommendations, or the report and any exhibits thereto pertaining to the prior demand. The special committee did not take up Stanley's counsel's offer to meet with the committee. The Company gave no indication it even considered the additional information submitted by Stanley; it implied it did not by stating the special committee's conclusion was "*based on the factual information the committee had gathered during the overall investigation* and applicable law." (Emphasis added).

145. Even assuming the special committee members were independent and disinterested, the Company provided Stanley with no basis to conclude the special committee conducted its inquiry in good faith and the committee's recommendation was the product of a thorough investigation. Instead, the February 6, 2014, Falk letter clearly implied the results of Stanley's demand were a foregone conclusion; the special committee did not investigate the additional matters raised by Stanley or if it did, gave them short-shrift; the special committee was uninterested in obtaining all relevant facts and considerations by declining to meet with Stanley's counsel; and the special committee and the Board had no intention of disclosing the details of the investigation and report to Stanley. The Falk letter did not even say whether the full Board

unanimously accepted the special committee's report and adopted its recommendation. In short, the Board simply stonewalled its shareholder's demand.

146. Plaintiff Erste made its demand by letter dated May 6, 2014. Exhibit 2. Erste formally demanded that the Board "immediately investigate and commence legal action for remedial and other relief against" the Diversion Defendants "for violating their fiduciary duties in connection with the allegations contained in the Verified Complaint in the case captioned *Stanley* v. *Arnold*, Case No. 1:12-cv-00482." The Demand Letter asserted that "[a]s a result of the misconduct detailed in the Complaint, the Company has suffered substantial financial injuries detailed in the Complaint, which have not been remediated. These damages and injuries to the Company occurred on the Director Defendants' watch and as a direct and proximate result of their failure to take steps to ensure satisfactory performance of its duties." The Demand Letter also repeated the three additional factors not directly at issue in *Stanley* reflecting potential misconduct by the Diversion Defendants that were set out in Stanley's October 23, 2013, demand letter, i.e., the extent to which the Diversion Defendants approved or otherwise were informed about the OAG Settlement Agreement and what they knew about the Company's compliance with its terms; the Diversion Defendants' knowledge regarding the 2008 MOA with the DEA and any efforts they made to ensure the Company complied with the settlement; and whether the Diversion Defendants were aware of any issues regarding the selling, marketing, or reporting of controlled substances in West Virginia.

147. The Demand Letter went on to say:

> Please be advised that it making these facts known to you, Erste-Sparinvest does not concede in any way that the current board of the Company or any member thereof is disinterested and independent.
>
> As set forth in this Demand, it is incumbent on the current board to hold accountable all those responsible for the harm done to the Company.

> As you know, a similar demand was made by Henry Stanley, Jr. in letters dated September 5, 2013, and October 23, 2013. . . . On February 6, 2014, you advised me that the Company had rejected the demand based upon the recommendation of an unnamed special committee of the Company's directors (the "Special Committee") and would not pursue any action against the Director Defendants. . . . Counsel for the Company and the Special Committee subsequently rejected my requests that the Company identify the members of the Special Committee and supply a copy of any report or documents prepared/reviewed by the Special Committee.
>
> If the Company plans to reject this new demand on the same grounds as Stanley's demand, please advise me at your earliest convenience. *If the Company denies the demand, we ask that the Company identify the members of the Special Committee, provide a copy of the Special Committee's Report, and any documents cited or referenced the Report.*
>
> Should you have any requests, questions, or concerns, please do not hesitate to contact us. We would appreciate an opportunity to meet with the Special Committee and/or its representatives before it reaches any final conclusions regarding any response to the Demand including any investigation it decides to conduct in response thereto.

Exhibit 2 (emphasis added).

148. By letter dated July 28, 2014, Falk advised Erste's counsel that the Demand Letter had "been transmitted to the same special committee of the Cardinal Health Board of Directors that considered the correspondence you presented earlier on behalf of Henry Stanley, Jr." The letter did not offer Erste's counsel the opportunity to meet with the special committee or its representatives or solicit any additional information Erste might have in its possession. Instead, the letter stated "[y]ou will be advised in due course of any conclusions reached and actions taken in response to the Erste . . . correspondence." Exhibit 16, attached hereto.

149. By letter dated November 14, 2014, Falk advised Erste that the Board had rejected its demand. The letter stated:

> As you know from previous communications, and from Cardinal Health's public filings, a special committee of the Cardinal Health Board of Directors had previously been appointed to investigate matters set forth in an earlier, similar

shareholder demand (the "First Demand"). Upon receiving the committee's findings and recommendations as to the First Demand, the Board determined to reject that demand as not being in the best interest of the Company. That action was taken and publicly disclosed by the Company prior to receipt of the September 5, 2013 correspondence from you advancing a similar demand on behalf of another shareholder [Stanley] (together with your later letter of October 23,2013, the "Second Demand").

The Second Demand was referred to the same committee. As explained in my letter to you dated February 6, 2014, the committee undertook additional work. Upon receiving the committee's findings and recommendations as to the Second Demand, the Board determined to reject the Second Demand as not being in the best interest of the Company. That action was taken and publicly disclosed by the Company prior to receipt of your May 6, 2014 correspondence relating to the Erste-Sparinvest demand, the third such demand concerning similar underlying allegations.

Turning to the Erste-Sparinvest Demand Correspondence, as I noted to you in my letter of July 28, 2014, it was referred to the same committee . . . .

In connection with its work regarding the First and Second Demands and the additional work that followed receipt of the Erste-Sparinvest Demand Correspondence, the committee has conducted an extensive investigation with the assistance of independent counsel (Milbank, Tweed, Hadley & McCloy LLP), including examining many thousands of pages of documents and conducting a large number of witness interviews as well as discussions with counsel in the First Demand and also you. At the conclusion of its most recent investigative activity, *the special committee informed the Board that, based on the factual information the committee had gathered during the overall investigation and applicable law*, it had concluded that it would not be in the best interest of the Company to pursue claims for breach of fiduciary duty against the persons named in the Erste-Sparinvest Demand Correspondence. Accordingly, the committee recommended that the Board not pursue the action requested by the Erste-Sparinvest Demand Correspondence.

At its meeting on November 5, 2014, the full Board considered the results of the special committee's investigation and its recommendations. After discussion and deliberation, *including consideration of the earlier work of the special committee*, the Board determined to accept the special committee's report and to adopt the committee's recommendation. Accordingly, the Board has determined to reject the demand set forth in the Erste-Sparinvest Demand Correspondence, and the purpose of this letter is to advise you of that determination.

Exhibit 5 (emphasis added).

150. Erste was not given the opportunity to meet with the special committee, provide it with information, or review its report and recommendations pursuant to a confidentiality agreement, as is customary in similar circumstances. The Board never informed Erste, for example, of the special committee's charter and authority; how many times the special committee met; how much work it performed on the first two demands and how much additional work, if any, was done in response to Erste's demand; who wrote the committee's report; whether the committee's report and recommendation was unanimous; and whether the full Board's vote to accept the special committee's report and adopt its recommendation was unanimous. In short, the Board deliberately kept Erste in the dark regarding nearly everything about its demand except for the results.

151. Notwithstanding Erste's demand that the Company investigate whether the Diversion Directors violated their fiduciary duties in connection with the allegations in the verified complaint in *Stanley*, Falk's November 14, 2014, letter did not indicate whether the special committee had investigated that issue, and if it did, what the special committee concluded.

152. Notwithstanding Erste's demand that the Company investigate the extent to which the Diversion Directors: "approved or otherwise were informed about the [Discontinuance]"; "received any information regarding the Company's compliance with the [Discontinuance] including, at a minimum, whether they received any reports from the Company's Chief Ethics and Compliance Officer regarding the diversion of pharmaceuticals"; and "received any reports regarding the efficacy of the Company's anti-diversion compliance measures adopted in connection with the [Discontinuance], Falk's November 14, 2014, letter did not indicate whether the special committee had investigated any of those questions or any of the other reporting duties

of the Chief Ethics and Compliance Officer, such as whether he had utilized his direct reporting lines to the CEO and to the Audit Committee or similar oversight committee of the Board established pursuant to the Discontinuance to advise them of diversion issues, and if it did, what the special committee concluded.

153. Notwithstanding Erste's demand that the Company investigate the extent of the Diversion Directors "knowledge regarding the ultimate settlement with the [DEA], and any efforts the Director Defendants made to ensure that the Company was in compliance with that settlement," Falk's November 14, 2014, letter did not indicate whether the special committee had investigated that issue, and if it did, what the special committee concluded.

154. Notwithstanding Erste's demand that the Company investigate its "alleged failure to report suspicious orders in West Virginia and determine whether the Di[version] Defendants were aware of any issues regarding the selling, marketing, or reporting of controlled substances in West Virginia," Falk's November 14, 2014, letter did not indicate whether the special committee had investigated that issue, and if it did, what the special committee concluded.

155. Notwithstanding Erste's demand that the Company provide it with a copy of the special committee's report, and any documents cited or referenced in the report, Falk's November 14, 2014, letter did not enclose or offer to provide any such materials.

156. Notwithstanding Erste's request "to meet with the Special Committee and/or its representatives before it reaches any final conclusions regarding any response to the Demand including any investigation it decides to conduct in response thereto," the special committee never sought Erste's input.

157. The Board has once again stonewalled a shareholder demand to investigate its wrongdoing. The special committee's response to Erste's demand was substantially similar to its

response to Stanley's demand, and demonstrates it was pre-disposed to deny Erste's demand and lacked good faith in conducting the investigation, *assuming one was even performed*.

158. By stonewalling and refusing to cooperate with both Erste and Stanley, the Demand Defendants have shown a pattern of refusing to respond to legitimate shareholder demands in good faith.

159. The Demand Defendants' referral of Erste's demand to a pre-existing special committee pre-disposed to reject its shareholder's demand while simultaneously shutting Erste out of the process and providing it with no information about the special committee, its deliberations, report, recommendations, and the Board's approval thereof, and denying Erste the chance to meet with the special committee and/or its representatives, is not subject to judicial deferral because there is no presumption in favor of the good faith of a special committee and it is impossible to determine whether any of the three criteria for judicial deference -- (1) the special committee is comprised of independent, disinterested trustees; (2) the special committee conducts its inquiry in good faith; and (3) the committee's recommendation is the product of a thorough investigation -- have been met.

160. Moreover, the failure to provide Erste with such information constitutes bad faith by the Demand Defendants.

161. Additionally, Demand and Diversion Defendant and special committee member King was one of the directors against whom Erste demanded formally demanded that the Board "investigate and commence legal action for remedial and other relief." His membership on the two-person special committee constituted a conflict of interest and demonstrated a lack of independence, because King faces a substantial likelihood of liability for his actions and inaction as a Diversion Defendant. This conflict was all the worse because there were other Demand

Defendants available to serve on the special committee who were not also Diversion Defendants (e.g., Demand Defendants Anderson and Hemingway Hall).

162. For these reasons, demand was improperly refused, and this action should be permitted to proceed on this basis.

VII. COUNT I

BREACH OF FIDUCIARY DUTIES AGAINST THE DEFENDANTS

163. Plaintiff incorporates by reference all preceding and subsequent paragraphs as if fully set forth herein.

164. Each of the Defendants, because of his or her position as a director and/or officer of Cardinal Health, owes and has owed fiduciary duties to the Company in connection with the management and operations of the Company's business and operations.

165. To properly discharge these duties, the Defendants are and were required to, among other things:

(a) manage, conduct, supervise, and direct the business affairs of Cardinal Health in accordance with best practices, applicable laws, rules, and regulations, and the terms of the MOA and all other government settlement agreements;

(b) neither violate nor permit any officer, director, agent, or employee of Cardinal Health to violate applicable laws, rules, or regulations, or the terms of the MOA and all other government settlement agreements;

(c) remain informed as to the status of Cardinal Health's business practices and operations and upon receipt of notice of information of imprudent or unsound practices or operations, make a reasonable inquiry in connection therewith, and take steps to correct such practices or operations; and

(d) conduct an investigation by independent, disinterested directors in good faith and produce a recommendation that is the product of a thorough investigation in response to a demand by a shareholder.

166. Moreover, each of the Diversion Defendants has and had a duty to Cardinal Health to establish and maintain adequate internal controls to ensure that the Company was operated in a prudent and lawful manner. The Diversion Defendants have and had an affirmative obligation to install an internal control system to discover wrongdoing. Additionally, where red flags exist, the Diversion Defendants have and had an obligation to take affirmative steps to address such issues.

167. As detailed herein, the Diversion Defendants caused and/or allowed the Company to violate federal and state statutes and regulations, and failed to properly and adequately maintain a system of internal controls sufficient to ensure the Company's compliance with, among other things, those laws and the MOA, in violation of their fiduciary duties, despite repeated warnings – the 2006 guilty plea in Texas by the rogue internet pharmacy owner; the December 26, 2006, $11 million settlement with OAG; the $34 million September 30, 2008, MOA with DEA; the May 15, 2012, ISO settlement with DEA, the conduct underlying which is the subject of civil fine discussions with DOJ and for which the Company has accrued $27 million; and the West Virginia action – that the Company had and has serious and continuing drug diversion problems. The Diversion Defendants instituted a corporate culture that encouraged unlawful and irresponsible activity resulting in the loss and continued loss of significant amounts of money, loss of business, and irreparable damage to the Company's reputation.

168. As a direct and proximate result of the Defendants' wrongful conduct and actions, Cardinal Health has suffered and will continue to suffer significant damage.

169. As a direct and proximate result of the Diversion Defendants' failure to perform their fiduciary obligations, Cardinal Health engaged in unlawful activities causing substantial damage to the Company.

170. The special committee's failure to conduct an independent investigation in good faith and produce a recommendation that was the product of a thorough investigation in response to Erste's demand, and the Demand Defendants' bad faith rejection of Erste's demand, breached the Demand Defendants' fiduciary duties to the Company.

171. This action is necessary for the Company to recover the harm caused by the Defendants' breaches of fiduciary duties.

VIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment as follows:

A. Authorizing the maintenance of this action as a derivative action, with Plaintiff as derivative plaintiff;

B. Declaring that the Defendants have violated their fiduciary duties to the Company;

C. Awarding against all of the Defendants and in favor of the Company the amount of damages sustained by the Company as a result of the Defendants' breaches of fiduciary duties;

D. Awarding to Plaintiff the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses; and

E. Granting such other and further relief as the Court deems just and proper.

IX. JURY DEMAND

Plaintiff demands trial by jury on all claims asserted herein.

Dated: January 23, 2015

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